



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Group Art Unit 1652

In re

Patent Application of

Rodney A. Welch, et al.

Application No. 10/786,445

Confirmation No.: 5346

Filed: February 25, 2004

Examiner: Unknown

"E. COLI O157:H7 C1-INH-BINDING
PROTEIN AND METHODS OF USE"

INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 CFR §1.97(b)

Commissioner for Patents
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Alexandria, VA 22313-1450

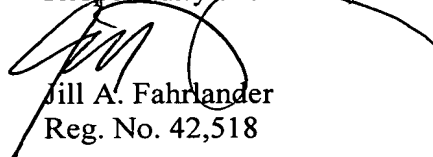
Sir:

The Examiner's attention is directed to the references which are listed on the attached Form PTO/SB/08A and/or PTO/SB/08B.

Citation of these references is respectfully requested.


No concession is made that these documents are prior art, and Applicant expressly reserves the right to antedate the documents as may be appropriate.

Respectfully submitted,

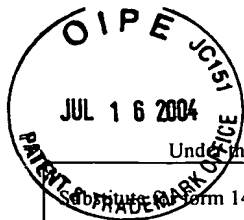

Jill A. Fahrlander
Reg. No. 42,518

File No. 096429-9141
Michael Best & Friedrich LLP
One South Pinckney Street
P. O. Box 1806
Madison, WI 53701-1806
(608) 257-3501

I, Leslie Lindsay Smith, hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of my signature.


Signature

14 July 2004
Date of Signature



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				Filing Date	February 25, 2004
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				Group Art Unit	1652
				Examiner Name	Unknown
Sheet	1	of	6	Attorney Docket Number	096429-9141
				Confirmation Number	5346

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

AA	Bauer, M. E. & Welch, R. A. (1996) "Characterization of an RTX Toxin from Enterohemorrhagic <i>Escherichia coli</i> O157:H" <i>Infect. Immun.</i> 64(1):167-175.
AB	Bergamaschini, L., G. Gobbo, S. Gatti, L. Caccamo, P. Prato, M. Maggioni, P. Braidotti, R. Di Stefano, and L.R. Fassati. (2001) "Endothelial targeting with C1-inhibitor reduces complement activation in vitro and during ex vivo reperfusion of pig liver" <i>Clin Exp Immunol</i> 126:412-420.
AC	Berggard, K., E. Johnsson, E. Morfeldt, J. Persson, M. Stalhammar-Carlemalm, and G. Lindahl. (2001) Binding of human C4BP to the hypervariable region of M protein: a molecular mechanism of phagocytosis resistance in <i>Streptococcus pyogenes</i> . <i>Mol Microbiol</i> 42(2):539-551
AD	Boucher, R.C. (2002) "An overview of the pathogenesis of cystic fibrosis lung disease" <i>Advanced Drug Delivery Reviews</i> , 54:1359-1371.
AE	Burland, V., Shao, Y., Perna, N. T., Plunkett, G., Sofia, H. J. & Blattner, F. R. (1998) "The complete DNA sequence and analysis of the large virulence plasmid of <i>Escherichia coli</i> O157:H7" <i>Nucleic Acids Research</i> 26(18):4196-4204.
AF	Burland, V., Shao, Y., Perna, N. T., Plunkett, G., Sofia, H. J. & Blattner, F. R. Accession T42131; T00210 (03 Dec 1999 # Sequence_revision; 03 Dec 1999 # text_change 17 Nov 2002) <i>Nucleic Acids Research</i> 26:4196-4204.
AG	Cai, S., and A.E. Davis, 3rd. (2003) "Complement regulatory protein C1 inhibitor binds to selectins and interferes with endothelial-leukocyte adhesion" <i>J Immunol</i> 171:4786-4791
AH	Caldwell, E.E., A.M. Andreasen, M.A. Blietz, J.N. Serrahn, V. VanderNoot, Y. Park, G. Yu, R.J. Linhardt, and J.M. Weiler. (1999) "Heparin binding and augmentation of C1 inhibitor activity" <i>Arch Biochem Biophys</i> 361:215-222.
AI	Caliezi, C., Wuillemin, W. A., Zeerleder, S., Redondo, M., Eisele, B. & Hack, C. E. (2000) C1-Esterase Inhibitor: An Anti-Inflammatory Agent and Its Potential Use in the Treatment of Diseases Other than Hereditary Angioedema" <i>Pharmacol. Rev.</i> 52(1):91-112.
AJ	Caprioli, A., Luzzi, I., Gianviti, A., Russmann, H. & Karch, H. (1995) "Pheno-genotyping of verotoxin 2 (VT2)-producing <i>Escherichia coli</i> causing haemorrhagic colitis and haemolytic uraemic syndrom by direct analysis of patients' stools" <i>J. Med. Microbiol.</i> 43:348-353.
AK	Catanese, J. & Kress, L. F. (1984) "Enzymatic Inactivation of Human Plasma C1-Inhibitor and α_1 - Antichymotrypsin by <i>Pseudomonas Aeruginosa</i> proteinase and Elastase" <i>Biochim. Biophys. Acta</i> 789:37-43.
AL	Chan, J.Y., C.E. Burrowes, F.M. Habal, and H.Z. Movat. (1977) "The inhibition of activated factor XII (Hageman factor) by antithrombin III: the effect of other plasma proteinase inhibitors" <i>Biochim Biophys Res Commun</i> 74:150-158.

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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AM	Cooper, N.R. (1991) "Complement evasion strategies of microorganisms" <i>Immunol Today</i> 12:327-331.
AN	Coutinho, M., K.S. Aulak, and A.E. Davis. (1994) "Functional analysis of the serpin domain of C1 inhibitor" <i>J Immunol</i> 153:3648-3654.
AO	Datsenko and Warner (2000) "One-step inactivation of chromosomal genes in <i>Escherichia coli</i> K-12 using PCR products" <i>PNAS</i> 97(12) 6640-6645.
AP	de Agostini, A., M. Schapira, Y.T. Wachtfogel, R.W. Colman, and S. Carrel. (1985) "Human plasma kallikrein and C1 inhibitor form a complex possessing an epitope that is not detectable on the parent molecules: demonstration using a monoclonal antibody" <i>Proc Natl Acad Sci U S A</i> 82:5190-5193.
AQ	Dean-Nystrom, E, <i>et al.</i> (2002) "Vaccination of Pregnant Dams with Intimin _{O157} Protects Suckling Piglets from <i>Escherichia coli</i> O157:H7 Infection" <i>Infection and Immunity</i> . 70(5):2414-2418.
AR	DeLoney, <i>et al.</i> (2002) "Role for Phosphoglucosyltransferase in <i>Vibrio fischeri</i> - <i>Euprymna scolopse</i> Symbiosis" <i>J. Bacteriology</i> , 184(18):5121-5129.
AS	DeLorenzo, V. D. & Timmis, K. N. (1994) "Analysis and Construction of Stable Phenotypes in Gram-Negative Bacteria with Tn5- and Tn10- Derived Minitransposons" <i>Bacterial Pathogenesis</i> , eds. Clark, V; L. & Bavoil, P. M. (Academic Press, San Diego), 235:386-405.
AT	Donnenberg, M.S. & Nataro, J.P. (1992) "Methods for Studying Adhesion of Diarrheagenic <i>Escherichia coli</i> " <i>Methods in Enzymology</i> , 253:324-327.
AU	Elson, C. & Ealding, W. (1984) "Generalized Systemic and Mucosal Immunity in Mice after Mucosal Stimulation with Cholera Toxin" <i>Journal of Immunology</i> , 132(6):2736-2741.
AV	Elson, C. & Ealding, W. (1984) "Cholera Toxin Feeding did not Induce Oral Tolerance in Mice and Abrogated Oral Tolerance to an Unrelated Protein" <i>Journal of Immunology</i> , 133(6):2892-2897.
AW	Eriksson, K., <i>et al.</i> (2003) "Cholera Toxin and Its B Subunit Promote Dendritic Cell Vaccination with Different Influences on Th1 and Th2 Development" <i>Infection and Immunity</i> , 71(4):1740-1747.
AX	Frank, M.M. (1992) "The mechanism by which microorganisms avoid complement attack" <i>Curr Opin Immunol</i> 4:14-19.
AY	Frank, M.M., and L.F. Fries. (1989) "Complement. In <i>Fundamental Immunology</i> " W.E. Paul, editor. Raven Press, New York.
AZ	Frankel, G., A.D. Phillips, I. Rosenshine, G. Dougan, J.B. Kaper, and S. Knutton. (1998) "Enteropathogenic and enterohaemorrhagic <i>Escherichia coli</i> : more subversive elements" <i>Mol Microbiol</i> 30(5):911-921.
BA	Gadek, J. E., Hosea, S. W., Gelfand, J. A., Santaella, M., Wickerhauser, M.,

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		Triantaphyllopoulos, D. C. & Frank, M. M. (1980) "Replacement Therapy in Hereditary Angioedema" <i>N. Engl. J. Med.</i> 302(10):542-546.
	BB	Gigli, I., T. Fujita, and V. Nussenzweig. (1979) "Modulation of the classical pathway C3 convertase by plasma proteins C4 binding protein and C3b inactivator" <i>Proc Natl Acad Sci U S A</i> 76:6596-6600.
	BC	Harlow, E., and D. Lane. (1988) Antibodies: a laboratory manual. Cold Spring Harbor Laboratory Press, Cold Spring Harbor.
	BD	Hauert, J., P.A. Patston, and M. Schapira. (2000) "C1 inhibitor cross-linking by tissue transglutaminase" <i>J Biol Chem</i> 275(19):14558-14562.
	BE	Hellwage, J., T. Meri, T. Heikkila, A. Alitalo, J. Panelius, P. Lahdenne, I.J. Seppala, and S. Meri. (2001) "The complement regulator factor H binds to the surface protein OspE of <i>Borrelia burgdorferi</i> " <i>J Biol Chem</i> 276(11):8427-8435.
	BF	Hong, Y.Q., and B. Ghebrehiwet. (1992) "Effect of <i>Pseudomonas aeruginosa</i> elastase and alkaline protease on serum complement and isolated components C1q and C3" <i>Clin Immunol Immunopathol</i> 62:133-138.
	BG	Huntington, J.A., R.J. Read, and R.W. Carrell. (2000) "Structure of a serpin-protease complex shows inhibition by deformation" <i>Nature</i> 407:923-926.
	BH	Jiang, H., E. Wagner, H. Zhang, and M.M. Frank. (2001) "Complement 1 Inhibitor is a regulator of the alternative complement pathway" <i>J Exp Med</i> 194:1609-1616.
	BI	Jiang, W. & Bond, J. S. (1992) "Families of metalloendopeptidases and their relationship" <i>FEBS Lett</i> 312(2,3):110-114.
	BJ	Judge, N., et al. (2004) "Plant Cell-Based Intimin Vaccine Given Orally to Mice Primed with Intimin Reduces Time of <i>Escherichia coli</i> O157:H7 Shedding in Feces" <i>Infection and Immunity</i> , 72(1):168-175.
	BK	Jung, C.-M., Matsushita, O., Katayama, S., Minami, J., Sakurai, J. & Okabe, A. (1999) "Identification of Metal Ligands in the <i>Clostridium histolyticum</i> CohH Collagenase" <i>J. Bact.</i> 181(9):2816-2822.
	BL	Karmali, M. A., Petric, M., Steele, B. T. & Lim, C. (1983) "Sporadic Cases of Haemolytic-Uraemic Syndrom Associated with Faecal Cytotoxin and Cytotoxin-Producing <i>Escherichia Coli</i> in Stools" <i>Lancet</i> 1:619-620.
	BM	Knutton, S., et al. (1989) "Actin Accumulation at Sites of Bacterial Adhesion to Tissue Culture Cells: Basis of a New Diagnostic Test for Enteropathogenic and Enterohemorrhagic <i>Escherichia coli</i> " <i>Infection and Immunology</i> , 57:1290-1298.
	BN	Kuno, K., Terashima, Y. & Matsushima, K. (1999) "ADAMTS-1 Is an Active Metalloproteinase Associated with the Extracellular Matrix" <i>Journal of Biological Chemistry</i> 274(26):18821-6.
	BO	Lathem, et al., (2004) "Potentiation of C1 Esterase Inhibitor by StcE, a Metalloprotease Secreted by <i>Escherichia coli</i> O157:H7" <i>J. Exp. Med.</i> 199(8) 1077-1087.

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BP	Lathem, W.W., T. Bergsbaken, S.E. Witowski, N.T. Perna, and R.A. Welch. (2003) "Acquisition of StcE, a C1 esterase inhibitor-specific metalloprotease, during the evolution of <i>Escherichia coli</i> O157:H7" <i>J Infect Dis</i> : in press.
BQ	Lathem, W.W., T.E. Grys, S.E. Witowski, A.G. Torres, J.B. Kaper, P.I. Tarr, and R.A. Welch. (2002) "StcE, a metalloprotease secreted by <i>Escherichia coli</i> O157:H7, specifically cleaves C1 esterase inhibitor" <i>Mol Microbiol</i> 45(2):277-288.
BR	Lee, G. <i>et al.</i> (1998) "Tau interacts with src-family non-receptor tyrosine kinases" <i>Journal of Cell Science</i> , 111:3167-3177.
BS	Li, Y., <i>et al.</i> (2000) "Human Response to <i>Escherichia coli</i> O157:H7 Infection: Antibodies to Secreted Virulence Factors" <i>Infection and Immunity</i> , 68(9):5090-5095.
BT	Makino, <i>et al.</i> , (1998) "Complete Nucleotide Sequences of 93-kb and 3.3-kb Plasmids of Enterohemorrhagic <i>Escherichia coli</i> O157PH7 Derived from Sakai Outbreak" <i>DNA Research</i> , 5, 1-9.
BU	Matsunami, K., S. Miyagawa, M. Yamada, M. Yoshitatsu, and R. Shirakura. (2000) "A surface-bound form of human C1 esterase inhibitor improves xenograft rejection" <i>Transplantation</i> 69:749-755.
BV	Mayer, M.M. (1961) <i>Experimental Immunochemistry</i> . E.A. Kabat and M.M. Mayer, editors. Thomas, Springfield, IL.
BW	Minta, J.O. (1981) "The role of sialic acid in the functional activity and the hepatic clearance of C1-INH" <i>J Immunol</i> 126(1):245-249.
BX	Molla, A., T. Akaike, and H. Maeda. (1989) "Inactivation of various proteinases inhibitors and the complement system in human plasma by the 56-kilodalton proteinase from <i>Serratia marcescens</i> " <i>Infect Immun</i> 57(6):1868-1871.
BY	Nataro, J.P., and J.B. Kaper. (1998) "Diarrheagenic <i>Escherichia coli</i> " <i>Clin Microbiol Rev</i> 11(1):142-201.
BZ	Oda, T., Y. Kojima, T. Akaike, S. Ijiri, A. Molla, and H. Maeda. (1990) "Inactivation of chemotactic activity of C5a by the serratial 56-kilodalton protease" <i>Infect Immun</i> 58(5):1269-1272.
CA	O'Farrell, P. H. (1975) "High Resolution Two-Dimensional Electrophoresis of Proteins*" <i>J Biol Chem</i> 250(10):4007-21.
CB	Paton, A.W., and J.C. Paton. (2002) "Reactivity of convalescent-phase hemolytic-uremic syndrome patient sera with the megaplasmid-encoded TagA protein of shiga toxigenic <i>Escherichia coli</i> O157" <i>J Clin Microbiol</i> 40(4):1395-1399.

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CC	Patston, P.A., and M. Schapira. (1997) "Regulation of C1-inhibitor function by binding to type IV collagen and heparin" <i>Biochem Biophys Res Commun</i> 230:597-601.
CD	Patston, P.A., M. Qi, J.A. Schifferli, and M. Schapira. (1995) "The effect of cleavage by a <i>Crotalus atrox</i> alpha-proteinase fraction on the properties of C1-inhibitor" <i>Toxicon</i> 33(1):53-61.
CE	Pensky, J., and H.G. Schwick. (1969) "Human serum inhibitor of C'1 esterase: identity with alpha-2-neuraminoglycoprotein" <i>Science</i> 163(3868):698-699.
CF	Perna, N. T., Plunkett III, G., Burland, V., Mau, B., Glasner, J. D., Rose, D. J., Kirkpatrick, H. A., Postal, G., Hackett, J., Klink, S., Boutin, A., Shao, Y., Miller, L., Grotbeck, E. J., Davis, N. W., Lim, A., Dimalanta, E. T., Potamouisis, K. D., Apodaca, J., Anantharaman, T. S., Lin, J., Yen, G., Schwartz, D. C., Welch, R. A. & Blattner, F. R. (2001) "Genome sequence of enterohaemorrhagic <i>Escherichia coli</i> O157:H7" <i>Nature</i> 409: 529-533.
CG	Pierce, N.F. (March 20, 1978) "The Role of Antigen Form and Function in the Primary and Secondary Intestinal Immune Responses to Cholera Toxin and Toxoid in Rats" <i>J. Exp. Med.</i> , The Rockefeller University Press, 195-206.
CH	Pixley, R.A., M. Schapira, and R.W. Colman. (1985) "The regulation of human factor XIIa by plasma proteinase inhibitors" <i>J Biol Chem</i> 260:1723-1729.
CI	Plunkett, G., 3rd, D.J. Rose, T.J. Durfee, and F.R. Blattner. (1999) "Sequence of Shiga toxin 2 phage 933W from <i>Escherichia coli</i> O157:H7: Shiga toxin as a phage late-gene product" <i>J Bacteriol</i> 181(6):1767-1778.
CJ	Potempa, J., E. Korzus, and J. Travis. (1994) "The serpin superfamily of proteinase inhibitors: structure, function and regulation" <i>J Biol Chem</i> 269(23):15957-15960.
CK	Potter, A., <i>et al.</i> (2004) "Decreased shedding of <i>Escherichia coli</i> O157:H7 by cattle following vaccination with type III secreted proteins" <i>Vaccine</i> , 22:362-369.
CL	Pouille, M., Burnouf-Radosevich, M. & Burnouf, T. (1994) "Large-scale preparation of highly purified human C1-inhibitor for therapeutic use" <i>Blood Coagulation & Fibrinolysis</i> 5:543-9.
CM	Roesch, P. L. & Blomfield, I. C. (1998) "Leucine alters the interaction of the leucine-responsive regulatory protein (Lrp) with the fim switch to stimulate site-specific recombination in <i>Escherichia coli</i> " <i>Molecular Microbiology</i> 27(4):751-61.
CN	Schapira, M., C.F. Scott, and R.W. Colman. (1982) "Contribution of plasma protease inhibitors to the inactivation of kallikrein in plasma" <i>J Clin Invest</i> 69:462-468.
CO	Schmaier, A.H., S. Amenta, T. Xiong, G.D. Heda, and A.M. Gewirtz. (1993) "Expression of platelet C1 inhibitor" <i>Blood</i> 82(2):465-474.
CP	Schmaier, A.H., S.C. Murray, G.D. Heda, A. Farber, A. Kuo, K. McCrae, and D.B. Cines. (1989) "Synthesis and expression of C1 inhibitor by human umbilical vein endothelial cells*" <i>J Biol Chem</i> 264(30):18173-18179.
CQ	Siegler, R.L., (1995) "The hemolytic uremic syndrome" <i>Pediatr Clin North Am.</i>

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		Dec;42(6):1505-29
	CR	Shreedhar, V., <i>et al.</i> , (2003) "Cholera Toxin Induces Migration of Dendritic Cells from the Subepithelial Dome Region to the T- and B-Cell Areas of Peyer's Patches" <i>Infection and Immunity</i> , 71(1):504-509.
	CS	Sim, R.B., A. Reboul, G.J. Arlaud, C.L. Villiers, and M.G. Colomb. (1979) "Interaction of I125-labelled complement subcomponents C1r and C1s with protease inhibitors in plasma" <i>FEBS Lett</i> 97(1):111-115.
	CT	Storm, D., J. Herz, P. Trinder, and M. Loos. (1997) "C1 inhibitor-C1s complexes are internalized and degraded by the low density lipoprotein receptor-related protein" <i>J Biol Chem</i> 272(49):31043-31050.
	CU	te Loo, D.M., L.A. Monnens, T.J. van Der Velden, M.A. Vermeer, F. Preyers, P.N. Demacker, L.P. van Den Heuvel, and V.W. van Hinsbergh. (2000) "Binding and transfer of verocytotoxin by polymorphonuclear leukocytes in hemolytic uremic syndrome" <i>Blood</i> 95(11):3396-3402.
	CV	te Loo, D.M., V.W. van Hinsbergh, L.P. van Den Heuvel, and L.A. Monnens. (2001) "Detection of verocytotoxin bound to circulating polymorphonuclear leukocytes of patients with hemolytic uremic syndrome. <i>J Am Soc Nephrol</i> 12:800-806.
	CW	Thern, A., L. Stenberg, B. Dahlback, and G. Lindahl. (1995) "Ig-binding surface proteins of <i>Streptococcus pyogenes</i> also bind human C4b-binding protein (C4BP), a regulatory component of the complement system" <i>J Immunol</i> 154:375-386.
	CX	van den Berg, R.H., M. Faber-Krol, L.A. van Es, and M.R. Daha. (1995) "Regulation of the function of the first component of complement by human C1q receptor" <i>Eur J Immunol</i> 25:2206-2210.
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Examiner Signature		Date Considered	
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